UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.
v.	)	97-10814-WGY
	)	
HOECHST MARION ROUSSEL, INC.	)	
and	)	
TRANSKARYOTIC THERAPIES, INC.,	)	
	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiff, Amgen Inc. (Amgen), for its amended complaint against defendants Hoechst Marion Roussel, Inc. (Hoechst) and Transkaryotic Therapies, Inc. (TKT) alleges as follows:

1. This is a civil action for a declaration of patent infringement. Jurisdiction is based on 28 U.S.C. §§ 1338 and 2201-2202. Venue is based on 28 U.S.C. §§ 1391 and 1400(b).

2. Amgen is a Delaware corporation having a principal place of business in Thousand Oaks, California.

3. Upon information and belief, Hoechst, a subsidiary of its German parent, Hoechst AG, is a Delaware corporation having a principal place of business in Bridgewater, New Jersey. Hoechst has been and is now engaged in business within this District.

4. Upon information and belief, TKT is a Delaware corporation having a principal place of business in Cambridge, Massachusetts.

5. Amgen was founded in 1980 with a vision of becoming a fully integrated biotechnology company that would develop, manufacture, and market cost-effective therapeutics based on cellular and molecular biology. For the first nine years of its struggling existence, it had no product to sell. However, by 1989 its pioneering research had led to the commercial introduction of its erythropoietin product, EPOGEN. Due to its therapeutic benefits, EPOGEN has become the most successful product of the biotechnology industry and has improved the quality of life of millions of patients throughout the world. Amgen has grown as a company from only a handful of employees in 1980 to several thousand employees worldwide. Despite its dramatic achievements, Amgen has yet to pay a cash dividend, preferring instead to increase shareholder value by investing in research and development on other breakthrough therapeutics that will address today's unmet medical needs.

6. The subject matter of this litigation is erythropoietin (EPO), which is a glycoprotein hormone that regulates the level of red blood cells in circulation by stimulating their production, as needed, in the bone marrow. A glycoprotein comprises a polypeptide backbone of amino acid residues having side chains of sugar (carbohydrate) residues linked to certain positions of the amino acid backbone.

7. In healthy adult humans, naturally occurring EPO is secreted by kidney cells and circulates in the bloodstream. The presence of EPO in the blood, and its biological function, have been known since the 1950s; however, EPO has never been isolated from human blood because it is present in only minuscule amounts. Some EPO collects in the urine, and in 1976 a

form of EPO was purified in extremely minute quantities from the pooled urine of aplastic anemia patients whose kidneys over-produce EPO in an attempt to alleviate the anemia. This urinary EPO (uEPO) has never been demonstrated to have usefulness as a therapeutic due to its scarceness and to the fact that enzymes in the urine degrade the molecule's carbohydrate side chains. For decades there existed an unmet medical need for a product having the biological properties of EPO, *i.e.*, the capability of stimulating red blood cell production in order to treat various forms of anemia. The search for such a product was ongoing since at least the 1950s, but, to date, no therapeutically useful EPO product has been isolated from a naturally occurring source.

8. With the advances of recombinant DNA technology in the early 1980s, it was hoped that if the DNA sequence encoding EPO could be found, EPO could be produced by genetically engineered cells outside of the body. Nevertheless, at that time the cloning of the human EPO gene was not expected, due in part to the limited information available on its amino acid structure. In fact, prior to Amgen's success, many groups of scientists of the highest caliber at various commercial and university research facilities had tried and failed to clone the EPO gene. Even if the gene had been available, however, there was no reasonable expectation that an EPO product produced using genetic engineering techniques would have the requisite biological activity needed to be a therapeutically useful product. One basis for the uncertainty was that uEPO was known to lose *in vivo* biological activity upon removal of portions of the carbohydrate side chains (deglycosylation). Thus, it was not known whether a human glycoprotein (such as EPO), which required proper glycosylation for full *in vivo* biological activity, could be successfully obtained from non-natural genetically engineered sources in an acceptably active form and in sufficient quantities to be therapeutically effective.

9. Amgen began its EPO research project sometime prior to August, 1981. In late 1983, Amgen's Dr. Fu-Kuen Lin, after using Herculean efforts and adopting a novel cloning approach, was the first to successfully isolate and identify the human EPO gene. This work enabled the determination of EPO's nucleotide (DNA) sequence, its entire amino acid sequence, and, for the first time, large-scale production of an EPO product that had the biological properties of human EPO. Dr. Lin's pioneering inventions have enabled Amgen to produce commercial quantities of therapeutically useful human EPO and to fulfill the long-felt, unmet medical need of hundreds of thousands of patients.

10. In 1989, Amgen received approval from the FDA to market EPO in the U.S. for the treatment of anemia associated with chronic renal (kidney) failure. Since that time, Amgen's licensee in the U.S. and abroad has expanded the therapeutic uses of EPO produced by Amgen or under license from Amgen to include the treatment of anemia caused by AIDS and cancer therapy. Amgen and its U.S. licensee currently meet and will continue to meet U.S. patients' needs for EPO. Today, almost 200,000 kidney dialysis patients in the U.S., whose chronic renal failure would otherwise result in debilitating symptoms of anemia, are benefitting from treatment with Amgen's EPO. Such treatment significantly improves the patients' quality of life by helping them regain the energy to enjoy normal activities of living and has almost completely removed the patients' dependence on blood transfusions--which carry the attendant risk of infection. Hundreds of thousands of other patients around the world are similarly benefitting from EPO treatments. Due to the dramatic therapeutic benefits of EPO, the worldwide market for EPO now is over three billion dollars. This tremendously successful therapeutic is available only as a result of Dr. Lin's pioneering inventions.

11. As disclosed in patent applications filed in 1983-84, Dr. Lin's inventive contributions were numerous. First, and foremost, Dr. Lin's work provided a therapeutically useful EPO product which was previously unavailable. In fact, this was the first known human EPO glycoprotein product which was not isolated from urinary sources. Second, Dr. Lin's work provided a process and starting materials for producing such an EPO product. This EPO was produced in vertebrate cells (*e.g.*, the previously well-characterized mammalian cells known as CHO cells). Another important aspect of Dr. Lin's work involved the greatly increased production of EPO by use of vertebrate EPO-producing cells that comprised amplified (increased number of copies) DNA encoding human EPO.

12. Recognizing the pioneering contributions made available by Dr. Lin's work and the extensive disclosure of that work in his patent applications, the U.S. Patent and Trademark Office has awarded Amgen a number of patents directed to Dr. Lin's inventions. The first patent to issue was U.S. Patent No. 4,703,008, which includes claims to a purified and isolated DNA sequence encoding human EPO. In 1989, in litigation between Amgen and Genetics Institute, this Court confirmed the validity and enforceability of Amgen's '008 patent claims directed to the isolated EPO gene that encodes human EPO, and in 1991 the Court of Appeals for the Federal Circuit affirmed that decision. Amgen continued to pursue protection for other aspects of Dr. Lin's inventive work as described and claimed in the original disclosures of the applications for the '008 patent by way of continuation patent applications. These continuation applications contained claims to EPO products and pharmaceutical compositions, to processes for making them, and to host cells capable of producing EPO in large quantities.

13. In 1989, three separate interferences were declared in the U.S. Patent and Trademark Office involving the issue of who was the first inventor of the subject matter claimed in Amgen's '008 patent and its pending patent application claims. These interferences involved claims arising from Dr. Lin's following inventions: (1) a purified and isolated DNA sequence encoding human EPO; (2) processes for preparing a human EPO glycoprotein product; and (3) the human EPO glycoprotein product itself. Each of these interferences was decided in Amgen's favor in 1991 and the resulting appeals were settled in Amgen's favor in 1993.

14. On August 20, 1996, U.S. Patent 5,547,933 ('933 patent) was duly and legally issued as a result of one of the Lin applications involved in the interference. This '933 patent includes claims to EPO glycoprotein products not isolated from a natural source. These claimed EPO products also have glycosylation which differs from that of human uEPO, and they can be made using any genetic engineering techniques. A copy of the '933 patent is attached as Exhibit A.

15. On April 8, 1997, U.S. Patent 5,618,698 ('698 patent) was duly and legally issued as a result of a Lin application directed to processes for making EPO. The '698 patent includes claims to a process for making EPO in vertebrate cells comprising promoter DNA, other than human EPO promoter DNA, that is operatively linked to DNA encoding human EPO to cause transcription of the DNA. The claims also are directed to processes that produce human EPO using vertebrate cells comprising amplified DNA encoding human EPO. As illustrated in the examples of the Amgen patents in suit, vertebrate cells were produced that had been manipulated to contain multiple copies of the EPO gene, thereby resulting in an increase in the amount of EPO produced by the cell. A copy of the '698 patent is attached as Exhibit B.

16. On April 15, 1997, U.S. Patent 5,621,080 ('080 patent) was duly and legally issued on a Lin application which includes claims to a human EPO glycoprotein product not isolated from human urine. Such products of the '080 patent can be made using any genetic engineering techniques, so long as human urine is not the source of the product. The '080 patent will expire on the same day as the '933 patent. A copy of the '080 patent is attached as Exhibit C.

17. On May 26, 1998, U.S. Patent 5,756,349 ('349 patent) was duly and legally issued on a Lin application which includes claims to *in vitro* vertebrate host cells capable of producing in excess of 100-1000 U of EPO per 10^6 cells in 48 hours. These cells have been genetically manipulated to contain non-human DNA sequences which control transcription of DNA encoding human EPO. A copy of the '349 patent is attached as Exhibit D.

18. On September 21, 1999 U.S. Patent 5,955,422 ('422 patent) was duly and legally issued on a Lin application which includes a claim directed to a pharmaceutical composition comprising human EPO. A copy of the patent is attached as Exhibit E.

19. Amgen is the owner by assignment of the patents identified in paragraphs 14-18 above, (hereafter "patents-in-suit") with full and exclusive right to bring suit to enforce these patents.

20. Upon information and belief, TKT commenced operations in 1988. As stated in its public pronouncements, TKT's focus in the field of therapeutic human proteins is to target currently-marketed, medically useful proteins that have been approved by health authorities and have achieved significant revenues in major markets. Amgen's EPO, the most successful biotech product to date, has been and continues to be TKT's prime and initial copycat target. In an

attempt to distinguish its product from Amgen's EPO, defendants call their EPO product "gene activated" EPO. Nevertheless, despite its new name, this EPO product and pharmaceutical compositions containing it, upon information and belief, have the amino acid structure and biological activity of the EPO disclosed and claimed in Amgen's patents-in-suit. Defendants' EPO is produced outside the body (*in vitro*) in genetically engineered mammalian vertebrate host cells comprising DNA encoding human EPO and a promoter (transcription controller) DNA sequence, other than human EPO promoter DNA, that is operatively linked to DNA encoding human EPO. These cells also comprise amplified DNA encoding EPO and thus can produce EPO in quantities in excess of 1000 U per 10^6 cells in 48 hours as determined by radioimmuno assay (RIA). TKT's published patent applications disclose the use of a human tumor cell as the EPO-producing cell. TKT's EPO product, like Amgen's, is not isolated from human urine and is not obtained from blood or some other natural source and, as such, is non-naturally occurring.

21. In order to commercialize its product, TKT has established pilot manufacturing facilities in Massachusetts, and has entered into collaborative agreements with Hoechst, the global pharmaceutical arm of Hoechst AG, whose pharmaceutical sales, reported to be DM 15 billion, places it among the world's three largest pharmaceutical companies according to Hoechst. By virtue of these collaborative agreements, TKT and Hoechst are partners in a joint effort to commercialize EPO in competition with Amgen's EPO. As a result of these agreements with TKT, Hoechst has invested or is obligated to invest some $58 million in TKT stock, up-front EPO license fees, and EPO milestone fees in addition to paying royalties to TKT on product sales, if any should occur. Overall, TKT has reported that it has the potential to receive up to $125

million from Hoechst in fees, equity investments, milestone payments, and research funding, not counting potential royalties.

22. According to these published TKT/Hoechst collaborative agreements, TKT is responsible for research on the process of making EPO and Hoechst is responsible for the worldwide development, manufacture, and marketing of EPO. As a part of the collaborative effort, TKT and Hoechst have formed jointly-staffed Research and Development Oversight Committees and Development Committees, and they hold joint Annual Review and Planning meetings. TKT has obligated itself to provide Hoechst with its EPO manufacturing know-how and to provide technical assistance to Hoechst in the manufacture, commercial production, and characterization of EPO, as well as to provide any other assistance requested by Hoechst.

23. In furtherance of its collaborative obligations to Hoechst, TKT has publicly announced that it has successfully generated a cell line and a process which has been scaled-up to achieve commercial production levels of EPO on behalf of Hoechst. TKT has more recently stated publicly that Hoechst's manufacturing capability (in kilogram quantities) is fixed and is at full commercial scale. Continuing to the present, TKT has reported that it has assisted and is continuing to assist Hoechst in its commercial EPO development activities and that it is conducting various studies focusing on EPO commercialization. Based on public pronouncements, Hoechst, with TKT's assistance, will complete its Phase III U.S. clinical studies by the end of this year in addition to continuing their other EPO commercialization activities. Final licensing approval from FDA is to be sought in early 2000 and production of EPO for commercial sale will begin at or before that date. TKT has acknowledged that Amgen's EPO product is well-known to regulatory authorities around the world for its safety and efficacy in humans, and that review of Hoechst's

regulatory license applications for its EPO product therefore is expected to be accomplished in a focused and expedited manner.

24. TKT and Hoechst have evidenced that they have the technical ability, the financial resources, the marketing and sales resources and know-how, and the contractual obligation to enter the U.S. market with a competing EPO product immediately upon receipt of regulatory approval. Relying on the fact that their EPO product has the same amino acid structure as Amgen's product and is alleged to be the bioequivalent of Amgen's product, TKT and Hoechst expect regulatory review to be substantially expedited.

25. TKT has made and used and will continue to make and use EPO in this country. The EPO made and used by TKT is a non-naturally occurring human EPO glycoprotein product having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells. This EPO glycoprotein, provided as a pharmaceutical composition, comprises the mature human EPO amino acid sequence of Figure 6 of the Amgen patents-in-suit. Further, like Amgen's EPO product, TKT's EPO glycoprotein is not isolated from human urine and, upon information and belief, has glycosylation which differs from that of human uEPO. TKT's EPO is produced in mammalian cells which produce EPO at the rate of at least 1000 U per 10^6 cells in 48 hours. Those cells comprise a non-human promoter (transcription control) DNA operatively linked for transcription to amplified DNA encoding the mature EPO amino acid sequence. Consequently, TKT's commercial making, selling, or using of EPO and/or its inducing of others to do so or its contributing to their doing so has or will constitute infringement of one or more of the claims of Amgen's patents-in-suit.

26. Hoechst has used and will continue to use EPO in this country, and has caused and will continue to cause others to make EPO in this country in furtherance of its efforts to market EPO in competition with Amgen. The EPO which is made for Hoechst in this country and is used by Hoechst in this country is a non-naturally occurring human EPO glycoprotein product having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells. This EPO glycoprotein, provided as a pharmaceutical composition, comprises the mature human EPO amino acid sequence of Figure 6 of the Amgen patents-in-suit, is not isolated from human urine, and, upon information and belief, has glycosylation which differs from that of human uEPO. Hoechst's EPO is produced in mammalian cells which produce EPO at the rate of at least 1000 U per 10^6 cells in 48 hours. Those cells comprise a non-human promoter (transcription control) DNA operatively linked for transcription to amplified DNA encoding the mature EPO amino acid sequence. Consequently, Hoechst's having EPO made for it commercially and its commercial use and sale of EPO has or will infringe one or more of the claims of Amgen's patents-in-suit.

27. Upon information and belief, the aforesaid acts of infringement have been or will be in willful disregard of Amgen's patent rights.

28. By reason of the aforesaid infringement by TKT and Hoechst, Amgen has suffered or will suffer damages and irreparable injury.

29. In August, 1996, one week after Amgen's '933 patent had issued, TKT released a Prospectus in connection with a 2.5 million-share offering in which it said its EPO technology avoided other patented approaches to protein production. No specific mention was made of Amgen's patents. On September 4, 1996, Amgen notified TKT and Hoechst in writing

that any implication made by or on their behalf that they will be able to commercialize their EPO in the U.S. would be materially false and misleading. In an Amended Prospectus dated October 4, 1996, TKT made reference to the Amgen letter in its section dealing with patent rights and represented that it did not infringe Amgen patents, including specifically Amgen's '933 patent. Following that denial of infringement, TKT and Hoechst have continued to fulfill their infringing mutual collaborative obligations in defiance of Amgen's patent rights.

30. There exists an actual, substantial, and continuing justiciable controversy between Amgen and TKT and Hoechst as to whether the EPO made by and for and used by TKT and Hoechst infringes Amgen's '933 patent. Further, despite Amgen's prior notice, TKT and Hoechst have continued and will continue to make, have made, and use EPO which is covered by Amgen's '933 and '080 patents, using processes covered by Amgen's '698 patent, in host cells covered by Amgen's '349 patent. Defendants' EPO product is contained in pharmaceutical compositions which are covered by Amgen's '080 and '422 patents assertion of said patents in this complaint, and TKT's repeated assertion that its technology is different from that claimed in Amgen's patents, there exists an actual, substantial, and continuing justiciable controversy between Amgen and TKT and Hoechst as to whether the aforesaid commercial activity of TKT and Hoechst has infringed or will infringe Amgen's patents-in-suit. Further, evidence of this controversy and its ripeness is apparent from TKT's pre-suit presentation to financial analysts, wherein TKT, upon information and belief, stated that they definitely do not infringe any of Amgen's patents and that "we are just waiting for Amgen to sue us so that we can get it over with," and by defendants' June 9, 1999 motion to reopen this suit.

31. The Amgen/TKT-Hoechst controversy regarding infringement of Amgen's patents-in-suit is concrete, not speculative, and ripe for adjudication. As shown by the preceding allegations and defendants' June 9, 1999 motion, the commercial process of making EPO which constitutes an infringement of Amgen's '698 patent has been finalized by the TKT/Hoechst collaboration, the host cells used to make EPO, and the EPO pharmaceutical composition itself, all as covered by Amgen's patents-in-suit are set and will not be changed. In addition to the other acts alleged in the preceding paragraphs, TKT and Hoechst have been, are, and inevitably will be taking further steps towards the early commercialization of EPO, all in furtherance of a firm, fixed, and highly publicized intent to market EPO in the U.S. immediately upon obtaining regulatory approval in defiance of Amgen's patent rights.

32. TKT and Hoechst, in furtherance of their collaboration, also have shown that this controversy is ripe for adjudication by embarking on a widely publicized campaign to pre-condition the market as to alleged shortcomings in the scope of Amgen's EPO patents and alleged advantages of the TKT/Hoechst EPO product. This campaign is evidenced by at least the following facts relating to misrepresentations about Amgen's EPO patent position:

(a) During much of its development of what the New York Times has reported as TKT's effort to "knockoff" Amgen's EPO product, TKT operated and talked as if Amgen's patent protection for EPO would be limited solely to its first-to-issue '008 patent which claims a purified and isolated human EPO gene. TKT has asserted that its technology does not require the human EPO gene to be isolated and introduced into a host cell. According to TKT, it avoids the need to isolate the EPO gene by using an immortalized human tumor cell line which, like all non-kidney human cells, contain a normally dormant copy of the EPO gene. Nonetheless, it is

essential to the gene activation technology employed by TKT that the nucleotide sequence of the human EPO gene, as discovered by Dr. Lin and provided in Amgen's patents, be known for TKT to be able to precisely insert its non-human promoter DNA sequence and accessory DNA sequences into the host cell nucleus and to operatively link those sequences to the DNA sequence encoding human EPO. Thus, TKT's technology fundamentally is derived from the information and principles described in Amgen's '008 patent.

(b) As early as 1994, TKT publicly announced that its process "absolutely eliminates the need to get a license on [Amgen's] gene patent." Thus, prior to the issuance of Amgen's '933 patent claiming non-naturally occurring EPO products, the relevant public was conditioned to accept as fact that TKT had evaded all Amgen patent protection.

(c) Whatever the basis for TKT's original noninfringement pronouncements to the trade and investment community, both TKT and Hoechst must have been aware of the '933 patent from August, 1996 because Amgen announced its issuance on August 21, 1996. Yet, since that date, TKT and Hoechst have reaffirmed their intention to proceed with commercialization of EPO. To Amgen's knowledge, TKT and Hoechst have not explained to the public how their EPO, unquestionably isolated from a non-natural source (*i.e.*, a genetically engineered cell grown in a commercial production facility), allegedly avoids infringement of Amgen's '933 patent covering non-naturally occurring EPO glycoprotein products.

(d) TKT did not acknowledge the issuance of the '933 EPO product patent in its Prospectus issued August 27, 1996 relating to its proposed 2.5 million-share offering. Rather, it vaguely represented that its technology avoided using patented approaches to protein production associated with "conventional" genetic engineering. Similar statements were made in TKT press

releases of August 30 and September 3, 1996. Upon information and belief, these representations were made with the intention of encouraging the purchase of TKT stock and helping to pave the way for Hoechst's early market entry by disparaging Amgen's EPO patent position.

(e) In its October 4, 1996 Amended Registration Statement, TKT represented that it had obtained a legal opinion "that the technologies employed by the Company and the method of their use in the Company's products do not infringe" Amgen's '933 patent. No mention was made in the Amended Prospectus of the fact that the '933 patent claims are directed to products and not to "technologies" or "methods." Upon information and belief, these TKT representations and omissions were made with the intention of encouraging the purchase of TKT stock and helping to pave the way for Hoechst's early market entry by conveying the impression that the TKT/Hoechst EPO product does not infringe Amgen's '933 patent while failing to make an unambiguous statement to that effect.

(f) In a New York Times article of October 17, 1996, TKT was again quoted as claiming its new technology for making proteins could "pierce the wall" of patent protection built up by biotechnology companies. Upon information and belief, this representation and the representations and omissions alleged in the preceding paragraphs disparaged Amgen's patent position and were intended to thereby enhance Hoechst's early market entry.

(g) On or before October 18, 1996, TKT raised some $37.5 million in its initial public stock offering, due at least in part to its representations that it was free and clear of Amgen's patents. Since that date, TKT's stock price has increased to the benefit of TKT and its shareholder Hoechst. The raising of funds through the public offering was intended to enhance Hoechst's early market entry by improving the financial health of its collaborator.

(h) Since the filing of Amgen's original complaint, defendants have collaborated in the preparation and filing of an application for FDA regulatory approval and are in the final stages of Phase III clinical studies of EPO. All of this activity in contemplation of commercial marketing of EPO has continued unabated in willful disregard of the subsequent issuance of Amgen's '698, '080, and '349 patents.

(i) In their June 9, 1999 motion, defendants admit there will be no "material process or product alteration" and assert that the Court need no longer be concerned with the issue of ripeness.

33. The concreteness of steps taken by TKT and Hoechst to enter the market, and consequent ripeness for adjudication is further evidenced by the following TKT representations as to its product's alleged advantages:

(a) In its August 27, 1996 Prospectus, TKT represented that it had produced a cell line sufficient for scale-up to achieve commercial EPO production levels and that its process was considered to be at least as efficient as, and maybe more cost-effective than, "conventional" techniques for protein production.

(b) In its October 4, 1996 Amended Registration Statement for its 2.5 million-share offering, TKT repeated the representation that TKT's cell line had been successfully used in "large scale" EPO manufacturing and that it was considered to be at least as efficient as, and maybe more cost-effective than, "conventional" genetic engineering techniques for protein production.

(c) More recently, upon information and belief, TKT has reported to analysts that Hoechst's manufacturing is at full commercial scale, capable of producing kilogram quantities of EPO at a favorable cost.

34. Upon information and belief, the above omissions, misrepresentations, and disparagements were made by TKT in furtherance of its obligations to and collaboration with Hoechst and are attributable to Hoechst.

35. By reason of their strong financial resources, their demonstrated commitment, their aggressive proselytizing of the market through misleading public pronouncements, their contractual obligations, and their expected advantages in FDA approval arising from the prior therapeutic success of Amgen's EPO product, as described in the preceding paragraphs, it is unquestionable that TKT and Hoechst, in collaboration, have demonstrated the existence of a controversy which is both concrete and ripe concerning whether the product and process of the TKT/Hoechst collaboration will infringe Amgen's patents when the collaboration enters the marketplace.

36. On June 9, 1999 defendants represented to the Court that the issues raised by Amgen's original complaint and defendants' answer thereto are ripe for adjudication. When Amgen joined in that representation, the Court ordered the action for declaratory judgment reopened. Thus, the issues of controversy and ripeness of an action for declaratory relief have become law of the case insofar as this amended complaint is concerned.

37. An actual justiciable controversy currently exists between the parties concerning whether TKT and Hoechst will infringe Amgen's patents-in-suit.

WHEREFORE, plaintiff prays:

1. That the Court enter judgment finding that the commercial making, having made, using, or selling of EPO and EPO pharmaceutical compositions, as complained of herein, has infringed or will constitute an infringement by TKT and Hoechst of Amgen's patents-in-suit, and that the Court further find that said infringement will continue unless enjoined;

2. That the Court declare the manufacture, causing to manufacture, importation, use, offer to sell, or sale of EPO and EPO pharmaceutical compositions, by TKT or Hoechst, as complained of herein, will constitute infringement of Amgen's patents-in-suit;

3. That the Court preliminarily and permanently enjoin TKT and Hoechst from commercially making, having made, importing, using, selling, or offering to sell any of the inventions claimed in Amgen's patents-in-suit as complained of herein;

4. That the Court find the complained-of commercial conduct by TKT and Hoechst to have been willful and declare this to be an exceptional case within the meaning of 35 U.S.C. §§ 284 and 285;

5. That the Court award Amgen its monetary damages and enhanced damages in an amount to be determined;

6. That the Court award Amgen its reasonable costs, expenses, and attorney fees herein; and

7. That the Court grant Amgen such other and further relief as is deemed just and proper.

Respectfully submitted,

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CERTIFICATE OF SERVICE
I hereby certify that a true copy of the above document was served upon the attorney of record for each other party by hand on October 7, 1999

Dated: October 7, 1999
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